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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,787	YUAN, CHONG-SHENG	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-9,13,18,19,23,24,28-31 and 36-56* is/are pending in the application.

4a) Of the above claim(s) *36-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8,9,13,18,19,23,24,28-31 and 51-56* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1, 4, 6-9, 13, 18-19, 23-24, 28-31, 36-56 are pending.

Applicant's amendment of claims 1, 4, 6-9, 13, 19, addition of claims 51-56, cancellation of claims 2-3, 5, 10-12, 14-17, 20-22, 25-27, 32-35 and a submission of a reference by Hershfield et al. (Science 216:739-742, 1982), in a communication filed on 5/11/2005 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/11/05 has been entered.

Claims 36-50 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected without traverse, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/28/2003.

Thus, claims 1, 4, 6-9, 13, 18-19, 23-24, 28-31, 51-56 are under consideration and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 4, 8-9, 13, 18-19, 23-24, 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is directed to a method for assaying Hcy, SAH or adenosine in a sample with a genus of mutant SAH hydrolases encoded by nucleic acids having specifically recited GenBank accession numbers. As known in the art, entries in GenBank can maintain the accession number even if there are modifications in the sequence. Therefore, the recitation of accession numbers render the instant claim indefinite in view of the fact that the sequence in the accession number may vary. Claims 4, 8-9, 13, 18-19, 23-24 and 28-31 are also rejected as being dependent upon claim 1. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31 remain rejected and new claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. This rejection has been discussed at length in previous Office Actions and it is now applied to new claims 52-56 for the reasons of record and those set forth below.

7. Applicants argue that the claims as amended are supported by structural features and by functional characteristics coupled with a known correlation between function and structure. Specifically,

applicants argue that the structural elements for these hydrolases are provided by the sequences recited. In addition, applicants submit that one of skill in the art would know how to create mutants having the desired properties based on the homology to the rat and human amino acid sequences. Applicants also submit that one human gene encoding SAH hydrolase has been identified and provide a reference by Hershfield et al. which discloses mapping of a human gene encoding SAH hydrolase.

8. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31 or avoid the rejection of new claims 52-56. The examiner acknowledges the amendments to the claims, the teachings of the specification, and the teachings of Hershfield et al. but disagrees with applicant's contention that the claimed invention is adequately described. Claims 1, 4, 8-9, 18-19, 23-24, 28-31 are directed to a method for assaying Hcy, SAH or adenosine in a sample with a genus of mutant SAH hydrolases encoded by nucleic acids having specific GenBank accession numbers, wherein said mutant SAH hydrolases have specific functional characteristics. Some of these GenBank entries disclose ESTs encoding partial proteins and SAH hydrolases of substantially different sizes from that of SEQ ID NO:1 (432 amino acids). The specification fails to teach the additional structural elements required in those ESTs such that they would encode a complete protein having SAH hydrolase activity. Also, while the specification may provide some guidance as to which amino acids can be mutated to obtain the desired functional properties if there is a significant level of homology between the exemplary mouse/human SAH hydrolases of the specification and the SAH hydrolase to be mutated, in the instant case, it is unclear as to how the teachings of the specification adequately describe the mutation of an SAH hydrolase of any size, such as that encoded by the sequence of GenBank entry AF129871, which is almost a quarter of the size of that of SEQ ID NO:1, based on the mutations disclosed for a 432 amino acid SAH hydrolase without an additional structural/functional correlation sufficient for one of skill in the art to identify those amino

acids which, when mutated, would provide an SAH hydrolase having the recited functional characteristics.

In regard to claims 6 and 52-56, these claims are directed to method for assaying Hcy, SAH or adenosine in a sample with a genus of mutant SAH hydrolases derived from human SAH hydrolases, wherein said mutant SAH hydrolases have specific functional characteristics. The claims encompass the use of mutants of any human SAH hydrolase. As such, it encompasses the mutation of known and unknown human SAH hydrolases. While Hershfield et al. maps a human gene encoding an SAH hydrolase, it is noted that there is no evidence to suggest that there is a single human SAH hydrolase. In humans, it is often found that there is more than one gene encoding proteins having the same enzymatic function, and more than one isoform of an enzyme. In the instant case, Hillman et al. (US Patent No. 5854023) discloses a human SAH hydrolase having 500 amino acids. Currently, the art teaches several human SAH hydrolases of different sizes, such as those disclosed in GenBank accession numbers CAH70965 (530 amino acids), CAH70966 (483 amino acids), and Q96HN2 (611 amino acids). Clearly more than one human SAH hydrolase exists, and there may be more yet to be discovered. The specification fails to disclose which structural elements of SEQ ID NO:1 would be required in any human SAH hydrolase or how SEQ ID NO;1 correlates with the structures of all possible human SAH hydrolases. Thus, for the reasons set forth above, one cannot reasonably conclude that the claimed invention is adequately described.

9. Claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31 remain rejected and new claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for assaying Hcy, SAH, or adenosine with a mutant SAH hydrolase wherein said SAH hydrolase comprises SEQ ID NO:1 and also has specific substitutions at the positions recited in claim 7, and those positions disclosed in the specification, wherein said mutant has the specific functional characteristics recited, does not provide enablement for method for assaying Hcy, SAH, or adenosine with a mutant SAH hydrolase

wherein said mutant SAH hydrolase is derived from (1) any human SAH hydrolase, (2) any SAH hydrolase where a substantial portion of its structure has not been disclosed , or (3) any SAH hydrolase where its complete structure is disclosed which does not have substantial structural homology to the mouse and human species disclosed in the specification. The specification does not enable any person of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

10. This rejection has been discussed at length in the previous Office Actions and it is now applied to new claims 52-56 for the reasons of record and those set forth below.

11. Applicants argue that the claims as amended are enabled. In particular, applicants assert that the sequence of each species is provided and the only known human SAH hydrolase sequence is also provided.

12. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 1, 4, 6, 8-9, 13, 18-19, 23-24, 28-31 or avoid the rejection of new claims 52-56. The examiner acknowledges the amendments to the claims, the teachings of the specification, and the teachings of Hershfield et al. but disagrees with applicant's contention that the claimed invention is fully enabled by the teachings of the specification. As discussed above, claims 1, 4, 8-9, 18-19, 23-24, 28-31 are directed to a method for assaying Hcy, SAH or adenosine in a sample with a genus of mutant SAH hydrolases encoded by nucleic acids having specific GenBank accession numbers, wherein said mutant SAH hydrolases have specific functional characteristics. Some of the GenBank entries recited in claim 1 disclose ESTs encoding partial proteins and SAH hydrolases of substantially different sizes from that of the SAH hydrolase of SEQ ID NO:2 (432 amino acids). The specification does not provide any information as to which additional structural elements are required in those ESTs such that they would encode a protein having SAH hydrolase activity. Also, it is reiterated herein that while the specification may provide some guidance as to which amino acids can be mutated to obtain the desired functional

properties if there is a significant level of homology between the mouse/human SAH hydrolases of the specification and the SAH hydrolase to be mutated, there is no teaching in the specification regarding how to mutate an SAH hydrolase of any size, such as that encoded by the sequence of GenBank entry AF129871, which is almost a quarter of the size of that of SEQ ID NO:1, based on the mutations disclosed for a 432 amino acid SAH hydrolase without an additional structural/functional correlation sufficient for one of skill in the art to identify those amino acids which when mutated would provide an SAH hydrolase having the recited functional characteristics. As known in the art, structure determines function. Thus, one of skill in the art would require some knowledge or guidance as to how to recognize in an SAH hydrolase of any size those amino acids which are key to obtain mutants having the desired functional characteristics.

Claims 6 and 52-56 are directed to method which requires a genus of mutant SAH hydrolases derived from human SAH hydrolases, wherein said mutant SAH hydrolases have specific functional characteristics. The claims encompass the use of mutants of any human SAH hydrolase. As indicated above, while the teachings of Hershfield et al. are acknowledged, there is no evidence to suggest that there is a single human SAH hydrolase. In fact, the art teaches more than one human SAH hydrolase, as evidenced by the teachings of Hillman et al. (US Patent No. 5854023) and GenBank accession numbers CAH70965 (530 amino acids), CAH70966 (483 amino acids), and Q96HN2 (611 amino acids), already discussed above, and there may be more not yet discovered. The specification fails to disclose which structural elements of SEQ ID NO:1 would be required in any human SAH hydrolase or how SEQ ID NO;1 correlates with the structures of all possible human SAH hydrolases. There is no teaching in the specification or the art in regard to the level of structural variability among all possible human SAH hydrolases and how that variability affects binding affinity to Hcy, SAH or adenosine. In the absence of this information, it is unclear as to how one of skill in the art can reasonably conclude that the teachings of the specification could apply to any human SAH hydrolase.

As previously discussed, the art clearly teaches how even small structural changes can affect function. See the teachings of Witkowski et al. and Seffernick et al. already discussed. Thus, in view of the amount of information provided, the lack of relevant examples, the lack of a structure/function correlation, and the unpredictability of the art in regard to structural changes and how they affect function, one of skill in the art would have to go through the burden of undue experimentation to enable the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 6 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuan et al. (J. Biol. Chem. 271 (45): 28009-28016, 1996). Yuan et al. teach a human placental SAH hydrolase which comprises the amino acid sequence as set forth in SEQ ID NO: 1 and that modification of three of the 10 cysteine residues per enzyme subunit resulted in complete inactivation of the enzyme. One of the three amino acids is Cys195. To verify whether Cys195 is important for the enzyme catalysis, Cys195 is replaced with serine or aspartic acid using site directed mutagenesis. Mutants of Cys195 (C195S and C195D) displayed drastically reduced (attenuated) enzymatic activity and severely altered the 3'-reduction potential as evidenced by the drastic reduction in the rate of [2,8-3H] Ado release. Yuan et al. assayed the assay of mutant enzyme as described on page 28010. This assay anticipates the instant claims as the detection of binding steps of the mutant SAH hydrolase with Hcy, SAH or adenosine in a sample as claimed herein is inherent in the detection of product step by the Yuan et al.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 6 remain rejected and new claims 51-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6376210. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 6 of the instant application is directed to a method for assaying homocysteine (Hcy), S-adenosylhomocysteine (SAH) or adenosine in a sample with a mutant SAH hydrolase, wherein said mutant SAH hydrolase is derived from a human SAH hydrolase, wherein said mutant SAH hydrolase has

binding affinity for Hcy, SAH or adenosine but has attenuated catalytic activity, and wherein said attenuated catalytic activity and/or binding affinity are caused by a mutation in the hydrolase's catalytic site, binding site for NAD, NADH, Hcy, SAH, adenosine, or a combination thereof, and wherein the mutant SAH hydrolase has a mutation in an amino acid which (a) participates in catalysis, (b) directly interacts with NAD, NADH, Hcy, SAH or adenosine, or (3) is adjacent to an amino acid which participates in catalysis or directly interacts with NAD, NADH, Hcy, SAH or adenosine. Claim 51 of the instant application is directed to the method of claim 6 with the added limitation that the human SAH hydrolase comprises SEQ ID NO: 1. Claim 52 of the instant application is directed to the method of claim 6 with the added limitation that the mutant SAH hydrolase has at least 50 fold higher binding affinity for Hcy, SAH or adenosine than the wild type SAH hydrolase from which it is derived. Claims 53-54 of the instant application are directed in part to the method of claim 6 wherein the sample is contacted with the mutant SAH hydrolase in the presence of a labeled SAH, SAH derivative or SAH analogue, wherein the label is a fluorophore, an enzyme or a protein. Claims 55-56 of the instant application are directed to the method of claim 6 with the added limitation that the mutant SAH hydrolase is labeled or immobilized.

Claims 1-16 of U.S. Patent No. 6376210 is directed to a method for assaying homocysteine in a sample with a mutant SAH hydrolase, wherein said hydrolase comprises the amino acid sequence set forth in SEQ ID NO: 1 (identical to SEQ ID NO: 1 of the instant application) and comprises any of the following mutations: F302S, K186A, H301D, R343A, D190A, F82A, T157L, N181D, the double mutation R431A and K426R, and/or a deletion at position 432, wherein said method comprises contact between the mutant SAH hydrolase and the sample, detection of binding between the mutant SAH hydrolase and Hcy, SAH or adenosine, and determination of the amount of Hcy in the sample. Since SEQ ID NO: 1 corresponds to a human SAH hydrolase and the mutations recited are taught in the

specification as resulting in a mutant SAH hydrolase having the recited functional characteristics, claims 1-16 of U.S. Patent No. 6376210 anticipate claims 6, 51-52 of the instant application as written.

Claim 6 of U.S. Patent No. 6376210 is directed to the method of claim 1 as described above, wherein SAH is contacted with the mutant SAH hydrolase in the presence of a labeled SAH, a derivative or an analogue thereof, such that the amount of labeled SAH bound to the mutant SAH hydrolase inversely relates to the amount of SAH in the sample. Therefore, claim 53 of the instant application is anticipated by claim 6 of U.S. Patent No. 6376210.

Claim 7 of U.S. Patent No. 6376210 is directed to the method of claim 6 with the added limitation that the labeled SAH is fluorophore labeled. As such, it anticipates claim 54 of the instant application as written.

Claims 8-9 of U.S. Patent No. 6376210 are directed to the method of claim 1 wherein the mutant SAH hydrolase is a labeled mutant SAH hydrolase, and wherein the label is a fluorescent label or an enzyme, therefore anticipating claim 55 of the instant application as written.

Claim 16 of U.S. Patent No. 6376210 is directed to the method of claim 1 with the added limitation that the mutant SAH hydrolase is immobilized. Therefore, it anticipates claim 56 of the instant application as written.

17. Applicants have requested to address this issue when other rejections are withdrawn.

18. It is noted that the claims originally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6376210 have changed in view of the amendments to the claims. Due to the fact that no arguments have been presented traversing the Examiner's position and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record and those set forth above.

Allowable Subject Matter

19. The subject matter of claim 7 appears to be allowable over the prior art of record. However, the claim is objected as it depends upon a rejected base claim.

Conclusion

20. No claim is in condition for allowance.

21. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. **THIS ACTION IS MADE NON-FINAL**. See M.P.E.P. ∋ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ∋ 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. ∋ 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Ph.D., Patent Examiner
Art Unit 1652
IC, July 24, 2005

REBECCA E. PROUTY
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